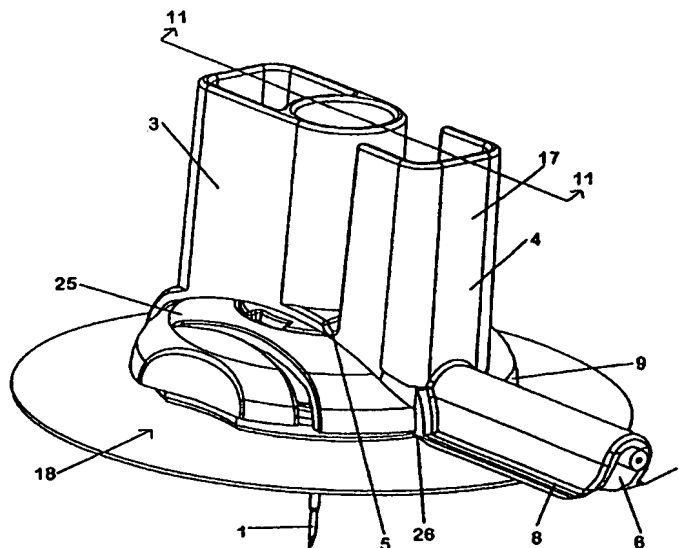




INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁷ : A61M 25/06	A1	(11) International Publication Number: WO 00/03757 (43) International Publication Date: 27 January 2000 (27.01.00)
<p>(21) International Application Number: PCT/DK99/00399</p> <p>(22) International Filing Date: 13 July 1999 (13.07.99)</p> <p>(30) Priority Data: 09/115,340 14 July 1998 (14.07.98) US</p> <p>(71) Applicant (for all designated States except US): MAERSK MEDICAL A/S [DK/DK]; Engmosen 1, DK-3540 Lyngø (DK).</p> <p>(72) Inventors; and (75) Inventors/Applicants (for US only): LARSEN, Bjørn, Guilak [DK/DK]; Åholmvej 2, Østød, DK-4000 Roskilde (DK). NIELSEN, Jan, Willum [DK/DK]; Åholmvej 2, Østød, DK-4000 Roskilde (DK). MATHIASSEN, Orla [DK/DK]; Åholmvej 2, Østød, DK-4000 Roskilde (DK). DELZAC, Marc [DK/DK]; Åholmvej 2, Østød, DK-4000 Roskilde (DK). TEISEN-SIMONY, Claude [DK/DK]; Ved Grensen 19, DK-2000 Frederiksberg (DK).</p> <p>(74) Agent: HOFMAN-BANG A/S; Hans Bekkevolds Allé 7, DK-2900 Hellerup (DK).</p>	<p>(81) Designated States: AE, AL, AM, AT, AT (Utility model), AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, CZ (Utility model), DE, DE (Utility model), DK, DK (Utility model), EE, EE (Utility model), ES, FI, FI (Utility model), GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SK (Utility model), SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).</p> <p>Published <i>With international search report.</i></p>	

(54) Title: **MEDICAL PUNCTURING DEVICE**

(57) Abstract

The invention relates to a medical puncturing device for use in connection with the insertion of a cannula where the cannula forms part of an infusion device, the medical puncturing device comprising a needle being at one end adapted for facilitating the puncturing and comprising at the opposite end a hub, the hub comprising a handle part and a shield part being pivotable in relation to the handle part and further comprising locking means on the shield part and the handle part, the locking means being adapted to interlock the shield and the handle part in a pivoted position of the shield part where the rigid needle is covered by this.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav Republic of Macedonia	TM	Turkmenistan
BF	Burkina Faso	GR	Greece	ML	Mali	TR	Turkey
BG	Bulgaria	HU	Hungary	MN	Mongolia	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MR	Mauritania	UA	Ukraine
BR	Brazil	IL	Israel	MW	Malawi	UG	Uganda
BY	Belarus	IS	Iceland	MX	Mexico	US	United States of America
CA	Canada	IT	Italy	NE	Niger	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NL	Netherlands	VN	Viet Nam
CG	Congo	KE	Kenya	NO	Norway	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NZ	New Zealand	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	PL	Poland		
CM	Cameroon	KR	Republic of Korea	PT	Portugal		
CN	China	KZ	Kazakhstan	RO	Romania		
CU	Cuba	LC	Saint Lucia	RU	Russian Federation		
CZ	Czech Republic	LI	Liechtenstein	SD	Sudan		
DE	Germany	LK	Sri Lanka	SE	Sweden		
DK	Denmark	LR	Liberia	SG	Singapore		
EE	Estonia						

TITLE

Medical puncturing device

5

BACKGROUND OF THE INVENTION

The present invention relates to a medical puncturing device for use in connection with the insertion of a cannula where the cannula forms part of an infusion device for e.g. subcutaneous delivery of a medication or a therapeutic fluid by means of an external infusion system and more particularly to a medical puncturing device capable of being discarded without the danger of causing unintended harmful injuries to persons afterwards.

The medical puncturing device will in the following be explained in connection with the field of subcutaneous infusion devices. Such infusion devices are generally known in the art for delivering a medication or a therapeutic fluid to a subcutaneous site in a patient. Such devices commonly comprise a soft tubular cannula extending from a housing adapted to receive the desired medication via means, e.g. disconnectable means, for suitable connection to further components of the infusion system. The possibility of disconnecting the infusion set from the further parts of the infusion system is provided in order to improve the user comfort. In order to place the soft cannula at a subcutaneous delivery site, a medical puncturing device comprising a rigid needle and a handle is used. The rigid needle is inserted through the hollow soft cannula and extends beyond the outer tip of this. The soft cannula is inserted into the subcutaneous fat layer of the patient together with the rigid needle, which is afterwards withdrawn leaving the soft cannula at

the infusion site. In order to provide such disconnectable medical puncturing devices and still maintain a fluid-tight sealing towards the interior of the housing and the tubular cannula that prevents contamination of the infusion site, such devices are commonly provided with a self-sealing penetrable septum on the housing. Upon withdrawal of the needle from the septum this provides a fluid-tight sealing towards the interior of the housing. The septum and the needle further provides a fluid-tight sealing between the housing and the connector means when medication or therapeutic fluid is delivered to the patient from the external infusion system. Subcutaneous infusion devices of this generally known type are known from e.g. US patent 5,522,803 to Teissen-Simony and US patent 5,545,143 to Fischell.

The use of a medical puncturing device comprising a needle may lead to some disadvantages during use of such device, viz. the potential danger of unintended exposure to the needle tip after the needle has been discarded.

A medical puncturing device of a type providing some remedy for these disadvantages is disclosed in US 5,533,974. This previously known device comprises a rigid needle and a protector housing wherein a biasing element, a cam and a gripping element are provided in order to lock the protector housing in relation to the needle at the pointed tip of this.

A further device is disclosed in US 5,279,591. This previously known device comprises a rigid needle and a protector housing wherein a resilient spring means is provided to block the needle tip upon sliding the protector housing to the needle tip.

A still further device is disclosed in WO 93/05840. This previously known device comprises a rigid needle and a protector housing wherein a resilient guard element is provided to block the pointed needle tip upon sliding the protector housing to the needle tip. Means for limiting the sliding movement are provided hereby ensuring the position of the protector housing.

Although these previously known medical puncturing devices to some extent give a satisfactory result with respect to the prevention of unintended and harmful needle sticks they all have a complicated construction requiring a cumbersome assembling process.

For this reason there is a need for improvements in the field of medical puncturing devices, the improvements relating to providing a medical puncturing device for an infusion device and having satisfactory properties particularly with respect to providing a medical puncturing device which can be dismantled and discarded without the risk of causing any injuries, and at the same time being of a simpler construction requiring less effort in the manufacturing process.

The device according to the invention remedies the above mentioned disadvantages and provides further advantages which will become apparent from the following description.

30

SUMMARY OF THE INVENTION

In order to provide remedy for the above mentioned disadvantages a medical puncturing device for use in combination with an infusion device has been developed, said medical puncturing device comprising a needle being

- at one end adapted for facilitating the puncturing and comprising at the opposite end a hub, the hub comprising a handle part and a shield part being pivotable in relation to the handle part and further comprising
- 5 locking means on the shield part and the handle part, the locking means being adapted to interlock the shield and the handle part in a pivoted position of the shield part where the rigid needle is covered by this.
- 10 By these features a simple construction is obtained which provides a reliable function as to preventing the risk of causing any injuries upon dismantling and discarding of the device.
- 15 In a preferred embodiment the shield part comprises a recess for accommodating the needle. This can conveniently be obtained by configuring the shield part with an essentially U-shaped cross section.
- 20 The locking means on the handle part preferably comprises two arms having on their opposed sides barbs adapted to interlock with the corresponding locking means of the shield part. The locking means on the shield part preferably comprises two side flanges adapted to
- 25 interlock with the corresponding locking means of the handle part. The flanges or the barbs are preferably tapered to facilitate the insertion of these into the corresponding locking means of the handle part and the shield part, respectively.
- 30 In order to facilitate the handling, the shield part preferably comprises an operating handle.
- The hub is conveniently configured as a single part where
- 35 the transition area between the handle part and the shield part is an area with a reduced rigidity, e.g. an

area with a reduced material thickness. The medical puncturing device according to the invention is preferably manufactured from a plastics material, e.g. by a moulding process.

5

In a convenient embodiment the hub is prior to pivoting of the shield part adapted to grip around a housing of an infusion device where a cannula belonging to this is to be inserted into a human body.

10

In a preferred embodiment is the needle bend, or kinked, when the shield part is interlocked with the handle part. The bend needle provides a biasing effect between the locking means, this providing additional safety against
15 inadvertent opening of the interlocked parts. Further, the needle hereby closely abuts on the inner side of the shield so that unintended contact with the needle is further avoided.

20

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view of a medical puncturing device;

25 FIG. 2 is a side view of the medical puncturing device shown in FIG. 1;

FIG. 3 is a rear end view of the medical puncturing device shown in FIG. 2;

30

FIG. 4 is a front end view of the medical puncturing device shown in FIG 2;

FIG. 5 is a bottom view of the medical puncturing device
35 shown in FIG. 1;

FIG. 6 is a top view of the medical puncturing device shown in FIG. 1;

FIG. 7 is a sectional view after the line 7-7 in FIG. 5;

5

FIG. 8 is a perspective view showing the medical puncturing device where the shield part is pivoted to a locked position;

10 FIG. 9 is a side view showing the shield part pivoted to a locked position;

FIG. 10 is a perspective view where the medical puncturing device is mounted on an infusion device, and

15

FIG. 11 is a sectional view after the line 11-11 in FIG. 10.

20

DESCRIPTION OF THE PREFERRED EMBODIMENT

From FIG. 1 a preferred embodiment of a medical puncturing device appears. The device comprises a needle 1 mounted in a needle hub 2. The needle is preferably
25 manufactured of a relatively rigid medical grade stainless steel material. The needle is at the end opposite the needle hub 2 pointed or tapered so as to facilitate puncturing e.g. by the insertion of a soft cannula. The needle hub comprises a handle part 3, which
30 is at one side connected to a shield part 4 via a hinge 5 formed as an area with a reduced thickness. The needle-covering portion of the shield part 4 has the shape of a half tube 6 with a general U-shaped cross section having at the edges at both sides flanges 7,8. The shield part 4
35 comprises a pivoting handle 17 arranged substantially perpendicular with respect to the half tube. At the

opposite side of the needle hub 2 in relation to the needle connection point the needle hub 2 comprises two arms 9,10 having barbs 11,12 at their opposed sides 15,16.

5

From FIG. 2 the puncturing device appears in a side view more clearly showing the transition area 5 where the shield part 4 is pivoted in relation to the handle part 3 by a pivoting action on the pivoting handle 17 by one
10 hand while holding the handle part 3 with the other hand.

Preferably the needle is formed with an opening 13 in the wall thereof and at a location which is to be mounted inside the housing of an infusion device (to be
15 described). This opening serves, when the puncturing device is connected to the housing of the infusion device, to prime the needle with medication before insertion into the patient. The opening 13 also serves to improve the flow of a sterilising gas through the needle.

20

From FIG. 3 and FIG. 4 which are rear and front end views, respectively, the locking elements on the shield part and the handle part appear more clearly. Upon pivoting of the shield part relative to the handle part,
25 in the direction of the needle, these locking elements are caused to interact.

FIGS. 5 and 6, which are bottom and top views, respectively, illustrate the locking elements in further
30 detail.

From FIG. 7 the fastening site 14 for the rigid needle in the hub becomes apparent. The needle is preferably secured in the correct position by a press fit connection
35 or by gluing or welding.

From FIGS. 8 and 9 it appears that the barbs 11,12 are co-operating with the flanges 7,8 of the shield part in order to interlock the shield part in the pivoted position. The deformed material in the transition area 5 together with the bend needle provide a biasing effect between the flanges 7,8 and the barbs 11,12. The needle hereby closely abuts on the side of the half tube 6 ensuring that unintended contact with the needle is avoided. This becomes especially clear in FIG. 9 where a part of the hub is cut away.

In the above disclosure of a preferred embodiment the locking means are disclosed as barbs and flanges, however, it is evident that any convenient type of interconnecting elements could be used.

From FIGS. 10 and 11 the puncturing device appears in combination with an infusion device. The puncturing device is inserted into the infusion device 18 for subcutaneous delivery of medication to a patient. This infusion device comprises a housing 19 in which a cavity 20 is provided and where a bore 21 having an outer opening leads medication from a pump or the like via a hose or tubing to the cavity 20 where a soft cannula 22 is provided in flow communication with the cavity 20 and where a further bore 23 covered with a self-sealing septum 24 is provided opposite the soft cannula 22. The housing in the disclosed embodiment comprises an additional connector 25 onto which the hose or tubing is connected, this allowing the hose or tubing to be disconnected from the housing portion mounted onto the skin surface of a patient. The disclosed connector comprises at its outer periphery a downwards oriented skirt portion, i.e. directed towards the skin of the patient, comprising a downwards facing edge.

The needle of the puncturing device is inserted through the self-sealing septum 24, the cavity 20 and the soft cannula 22 and extends beyond the outer distal tip portion of the soft cannula. The puncturing device is held in place in relation to the infusion device (here: the connector part 25) by gripping means in the form of barbs 26,27 on the shield part as well as barbs 11,12 on the handle part. When pivoting the operating handle 17 against the handle part 3 the barbs 26,27 will release from their gripping position on the downward facing skirt edges of the connector 25 and the puncturing device may be retracted from the infusion set. The soft cannula is placed in an operational position by penetrating the skin and subcutaneous tissue of the patient by means of the puncturing device and afterwards retracting the puncturing device through the soft cannula, the cavity and the self-sealing septum. The puncturing device is not intended for further use and should therefore be folded and brought into a locked position as shown in FIGS. 8 and 9 prior to discarding hereby ensuring that unintended harmful injuries caused by an exposed needle are avoided.

In the above disclosure of a preferred embodiment the gripping means are disclosed as barbs on the puncture device and co-operating edge portions on a connector, however, it is evident that any convenient type of interconnecting gripping elements could be used in order to establish a releasable connection between the infusion device and the puncturing device. The gripping means does not have to be of the positive-engagement type, but could also rely upon friction alone.

Claims:

1. An infusion device comprising:
- 5 a housing (19);
- an opening in said housing for leading medication to said housing;
- 10 a cannula (22) extending from the housing and being in flow communication with the opening, said cannula having an outer tip portion;
- 15 a puncturing device adapted to be releasably connected to said housing, said puncturing device comprising a hub (2) and a needle (1);
- said hub comprising a handle part (3) and a shield part
- 20 (4), said shield part being pivotable in relation to the handle part; and
- said needle comprising a distal end being adapted for facilitating puncturing, said needle being connected to
- 25 said handle part proximally of said distal end, said needle being adapted to extend through the cannula and beyond the outer tip portion thereof when the puncturing device is connected to said housing;
- 30 said hub further comprising corresponding locking means on the shield part and the handle part, the locking means being adapted to interlock the shield and the handle part in a pivoted position of the shield part relative to the handle part when the puncturing device is disconnected
- 35 from the housing, whereby the distal end of the needle is covered by the shield.

2. An infusion device as claimed in claim 1, wherein the shield part comprises a recess for accommodating the needle, or wherein the shield part
5 comprises a half-tube (6) having a generally U-shaped cross section for accommodating the needle.

3. An infusion device as claimed in any of the proceeding claims, wherein the locking means on the
10 handle part comprises two arms (9,10) having on their opposed sides barbs (11,12) adapted to interlock with the corresponding locking means (7,8) on the shield part.

4. An infusion device as claimed in claim 3,
15 wherein the barbs comprise tapered portions so as to facilitate interlocking with the corresponding locking means on the shield part.

5. An infusion device as claimed in any of the proceeding claims, wherein the locking means on the
20 shield part comprises two side flanges (7,8) adapted to interlock with the corresponding locking means (11,12) on the handle part.

25 6. An infusion device as claimed in claim 5, wherein the flanges comprise tapered portions so as to facilitate interlocking with the corresponding locking means on the handle part.

30 7. An infusion device as claimed in any of the proceeding claims, wherein the shield part comprises an operating handle (17), the operating handle being pivotable with respect to the handle part (3) of the hub.

35 8. An infusion device as claimed in any of the proceeding claims, wherein the hub is formed as a single

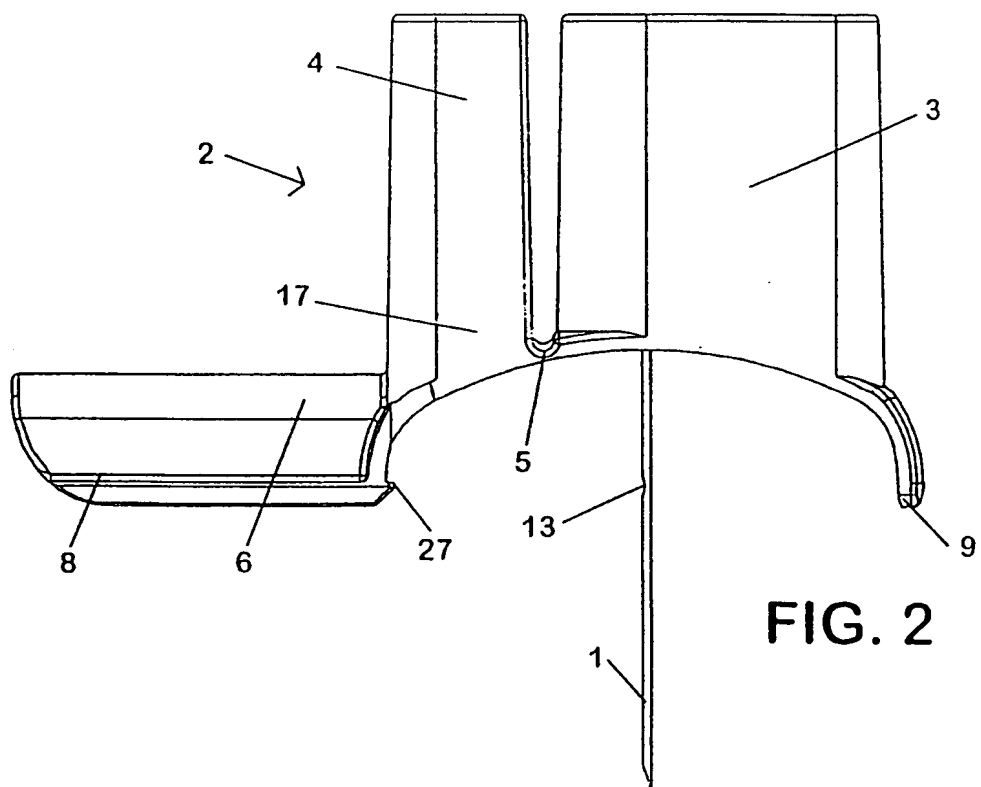
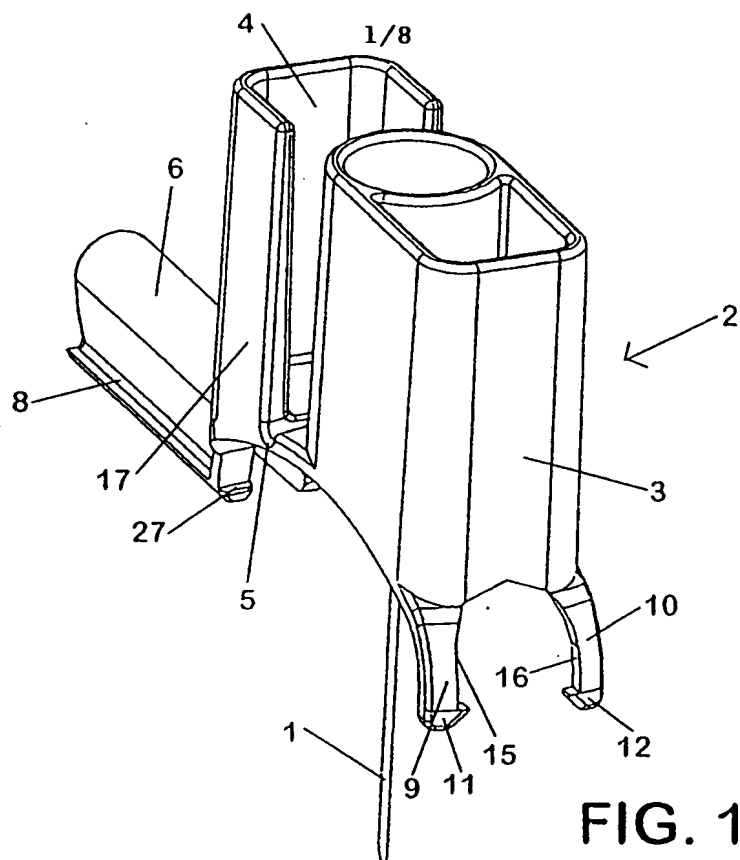
part and where a transition area (5) between the handle part and the shield part is adapted to function as a hinge portion and thereby to allow pivoting of said shield relative to said handle part, said transition area
5 preferably being an area with a reduced rigidity.

9. An infusion device as claimed in any of the proceeding claims, wherein said hub and said housing further comprise co-operating gripping means, said
10 gripping means being adapted to releasably interlock the hub and the housing.

10. An infusion device as claimed in claim 9, wherein the gripping means (26,27) on the hub are
15 provided at least on the shield part, wherein the shield part comprises an operating handle (17), the operating handle being pivotable with respect to the handle part of the hub, and wherein, when the puncturing device is connected to the housing, pivoting of the operating
20 handle against the handle part will release the gripping means on the shield part from the corresponding gripping means on the housing so as to facilitate removal of the puncturing device from the housing.

25 11. An infusion device as claimed in any of the proceeding claims, wherein the needle is bend or kinked when the shield part and the handle part is locked together;

30 whereby the bend needle provides a biasing effect between the locking means on the shield part and the handle part, and whereby the bend needle closely abuts on the shield to ensure that unintended contact with the needle is avoided.



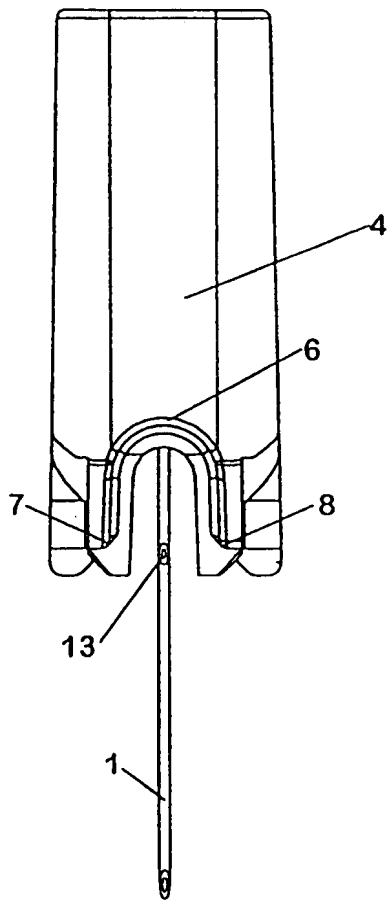


FIG. 3

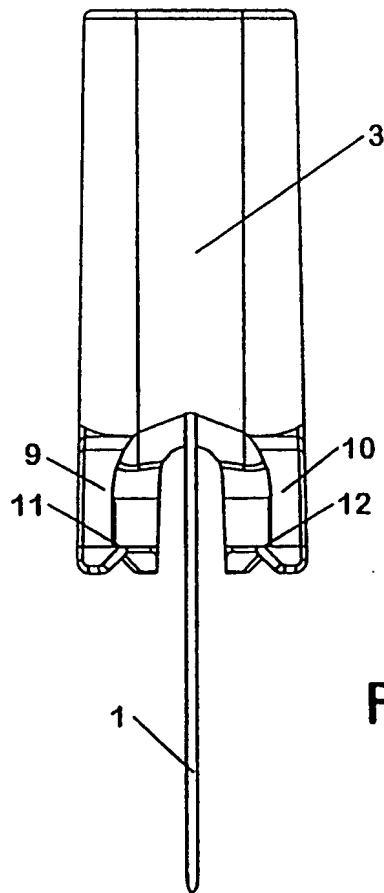


FIG. 4

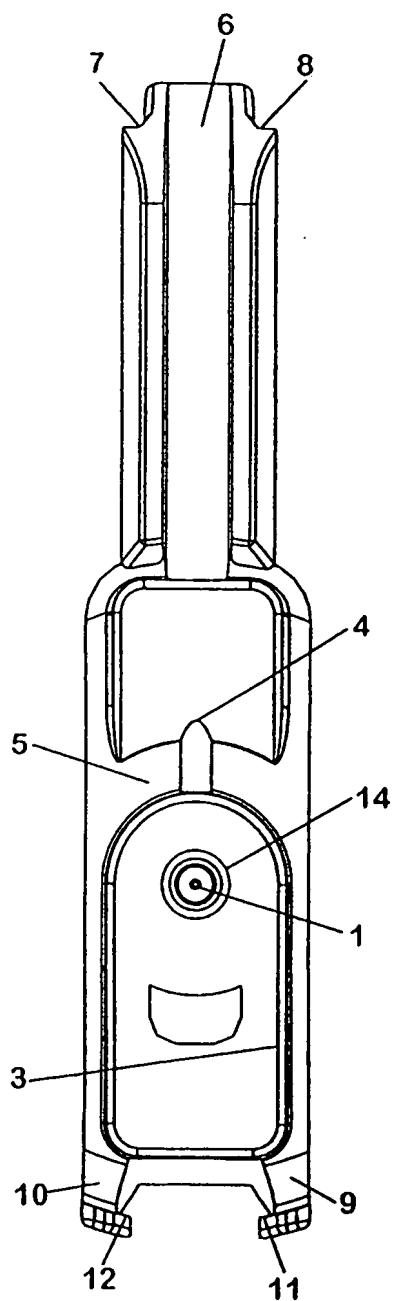


FIG. 5

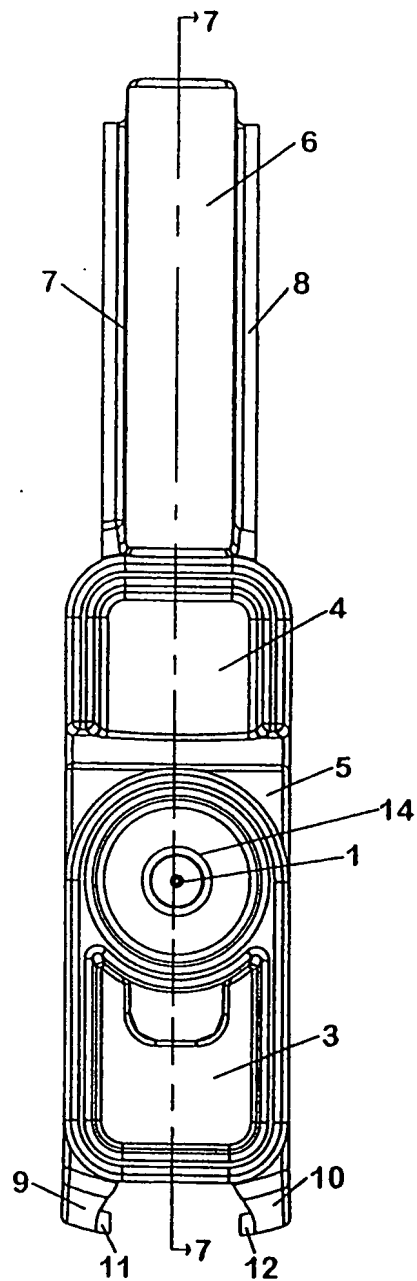


FIG. 6

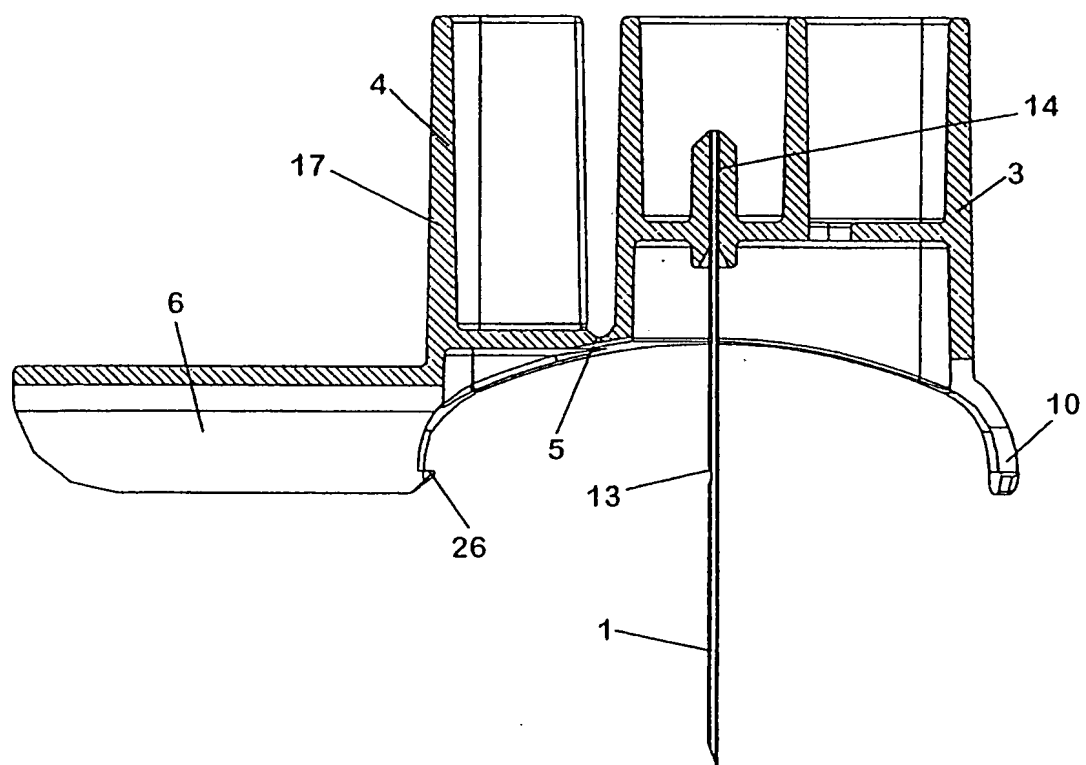


FIG. 7

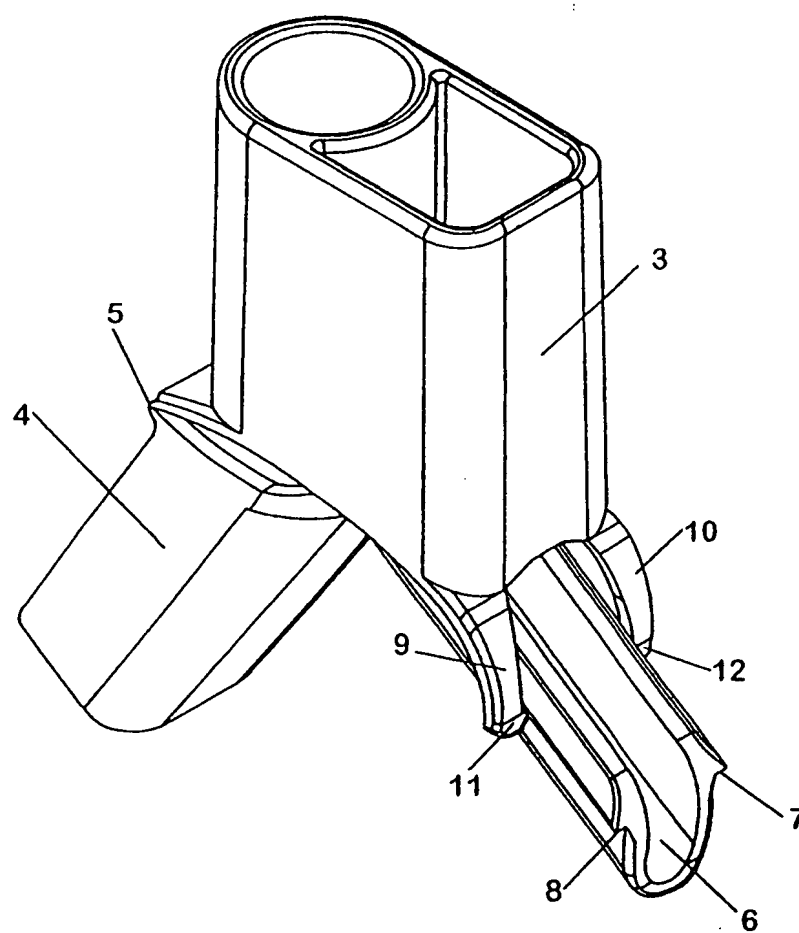


FIG. 8

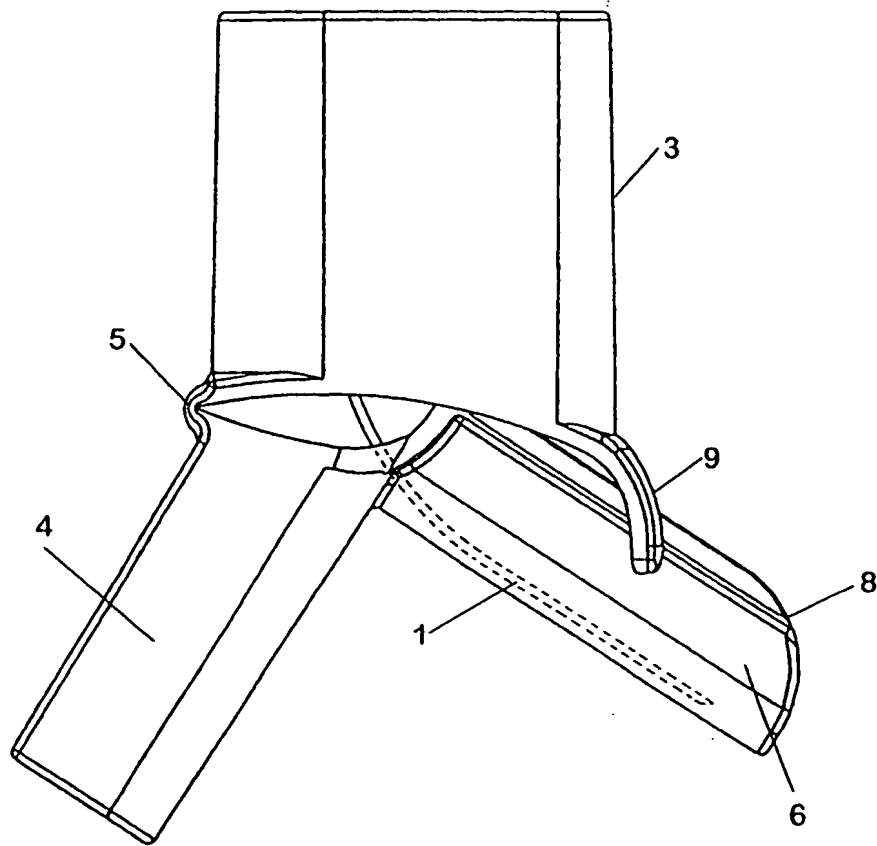


FIG. 9

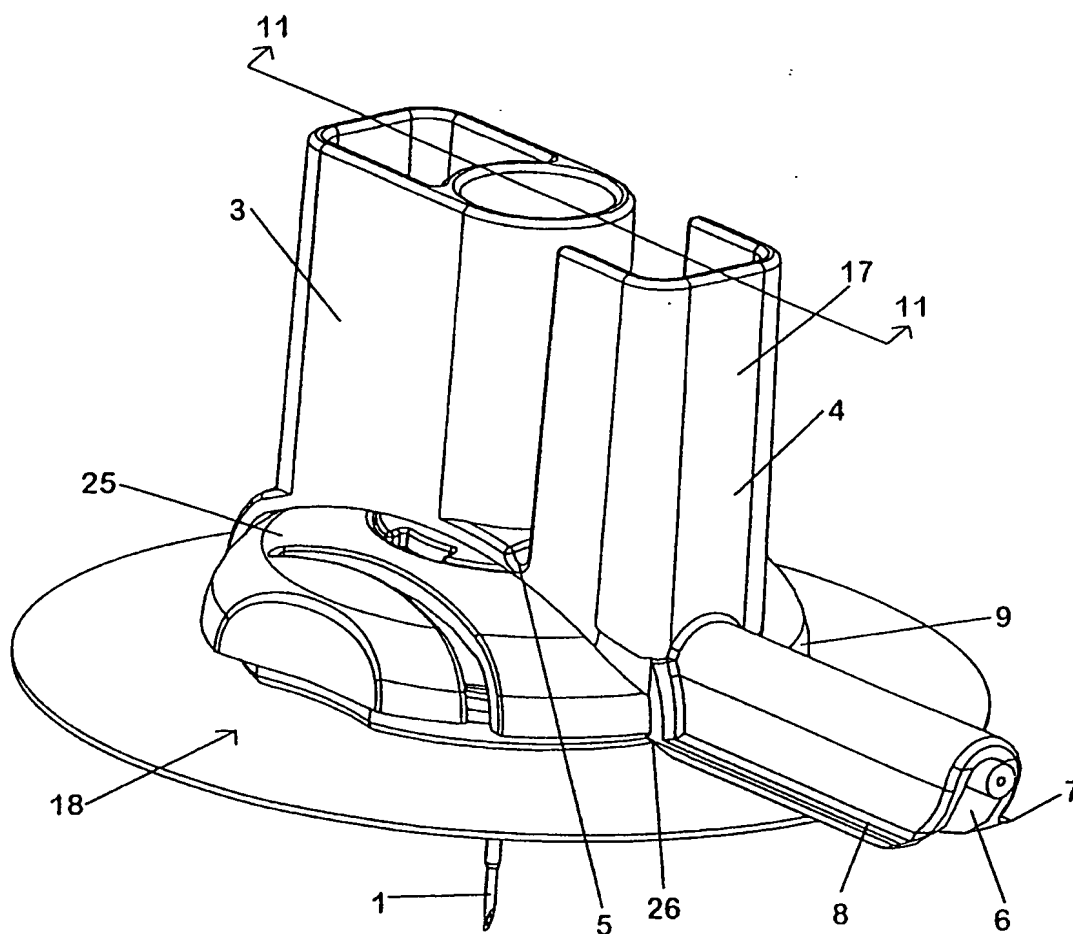


FIG. 10

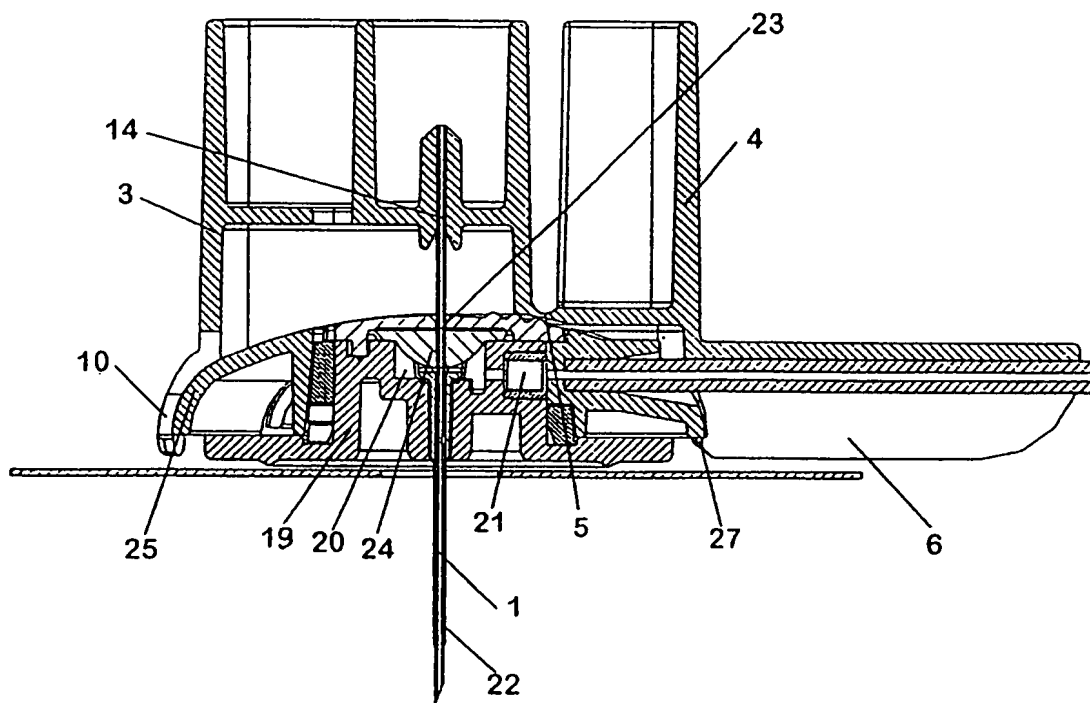


FIG. 11

INTERNATIONAL SEARCH REPORT

International Application No

PCT/DK 99/00399

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61M25/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 011 475 A (OLSON RICHARD A) 30 April 1991 (1991-04-30) figures 7 to 9 and the related description ---	1-8
A	EP 0 744 183 A (BECTON DICKINSON) 27 November 1996 (1996-11-27) the whole document ---	1-16
A	FR 2 725 902 A (M2CT) 26 April 1996 (1996-04-26) the whole document ---	1-11
A	US 5 176 662 A (BARTHOLOMEW GERALD ET AL) 5 January 1993 (1993-01-05) the whole document --- -/-	1-11

☒ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.

* Special categories of cited documents:

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

- "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
- "A" document member of the same patent family

Date of the actual completion of the international search

28 October 1999

Date of mailing of the international search report

04/11/1999

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Clarkson, P

INTERNATIONAL SEARCH REPORT

Inter national Application No

PC1/DK 99/00399

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	<p>US 5 545 143 A (FISCHELL DAVID R) 13 August 1996 (1996-08-13) cited in the application the whole document -----</p>	1-11

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/DK 99/00399

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5011475 A	30-04-1991	NONE	
EP 744183 A	27-11-1996	US 5584816 A CA 2174828 A JP 2882470 B JP 8322932 A	17-12-1996 26-11-1996 12-04-1999 10-12-1996
FR 2725902 A	26-04-1996	NONE	
US 5176662 A	05-01-1993	NONE	
US 5545143 A	13-08-1996	EP 0615768 A	21-09-1994